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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,596	04/13/2001	Hideji Tajima	10287.34	9347

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EXAMINER

CROSS, LATOYA I

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 08/10/2004

Office Action Summary

Application No.

09/807,596

Applicant(s)

TAJIMA ET AL.

Examiner

LaToya I. Cross

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1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION***Election/Restrictions***

Applicants' election of group I, claims 1-30 is acknowledged. However, after consideration of Applicants' remarks, the Examiner has agreed and the restriction requirement is withdrawn. All pending claims (1-31) have been examined in this Office Action.

Claim Observations

- Claim 17 contains the phrase "said discharge section" for which there is no antecedent basis. The claim should be amended to be dependent on another claim that has antecedent basis for the limitation.
- Claim 25 contains the phrase "the vibration strength, vibration period pattern, vibration time..." for which there is no antecedent basis. The claim should be amended to be dependent on another claim that has antecedent basis for the limitation.
- Claim 28 is directed to a method of controlling an automatic separator. The body of the claims begins by reciting the components of the automatic separator (lines 3-12). The method steps follow the components (lines 13-24). To make the claim clearer, it is suggested that Applicants include the phrase, "wherein the method includes" or similar language at the end of line 12 just before the method steps are recited.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 5, 6, 9-12, 17-29 and 31 rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,335,166 to Ammann et al.

Ammann et al teach an automatic analyzer comprising computer controller 1000 for running high-level analyzer controlling software and a microprocessor for controlling the low-level analyzer functions (col. 9, lines 19-31). The computer controller and microprocessor are equivalent to Applicants' claimed operation/control section. The system also comprises a plurality of reaction receptacles 160,162 (vessels) and a transport mechanism 500,502 (vessel moving means) for retrieving the receptacles. Further, a shuttle assembly (conveying means) and a specimen ring 250 are provided to move the receptacles along a receptacle advancement path (col. 9, lines 41-54; col. 10, lines 5-21). With respect to Applicant's claimed liquid processing section and separator, Ammann et al teach a magnetic moving structure 810 for subjecting the contents of the receptacles to a magnetic field (by magnetic structures on the sides of the receptacles as recited in claim 12), thereby causing magnetic particles in the receptacles to be drawn to the sides of the receptacles and the non-magnetic fluid to be unaffected. Thus, the magnetic moving structure is equivalent to Applicants' separator because the target analytes can be isolated. The target analytes are removed from the separated liquid by aspirator tubes 860. The aspirator is equivalent to the liquid processing means because it removes liquid from the receptacles. See col. 41, line 24 - col. 42, line 12. With respect to claim 3, Ammann et al teach a mixer 400 for agitating

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the contents of the receptacle. At col. 26, lines 17-21, the reference teaches that the mixer may operate by rotation or other techniques such as vibration and inversion.

With respect to claim 5, Ammann et al teach that the receptacles are part of a specimen ring which is rotatably driven by a motor. With respect to claim 9, Ammann et al teach a specimen pipette assembly or robot 450 positioned above the specimen ring 250 and pipette tip wheel, containing nozzles. The specimen pipette assembly is movable in an X,Y,Z motion to access reagent fluids and the receptacles (col. 10, line 55 – col. 11, line 23. With respect to claim 11, Ammann et al teach that several sensors are mounted on the bulk fluids provided in reagent bottles. Upper sensors indicate when the bottles are full, while lower sensors indicator when the bottles are empty (col. 17, line 66- col. 18, line 4; lines 53-67). With respect to claims 18-21, the aspirator tubes of the reference are disclosed as extending through a tube holder (main body) to which tubes are secured and extending through openings of the tube holder. The aspirator tubes have aspirator hoses which are lowered by a lift motor and drive screw (plunger) until frictionally engaged in a triplet. See col. 39, line 61 – col. 40, line 47. With respect to claim 26, the reference teaches that several incubators 600,602,604,606 are provided and transport mechanism can insert the receptacles into the incubator or retrieve the receptacles from the incubator (col. 12, lines 47-53). With respect to the method of claims 28 and 29, Ammann et al details the steps for carrying out an assay using the system described, wherein the computer receives instructions from an operator, the receptacles are introduced into the transport mechanism, reagents are dispensed, the mixer agitates the contents, the contents are separated using a magnetic field, the target analytes are removed and the receptacles are further moved along the processing path.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 4, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ammann et al in view of US Patent 6,017,721 to Butz.

Ammann et al fails to teach using microplates (claim 4) or centrifugation for separation (claim 7). With respect to the vessels being microplates, it would have been obvious to one of ordinary skill in the art to use microplates in Ammann et al instead of test tubes to allow for several small samples to be analyzed as one time. Such is advantageous when only a small amount of sample is available and when several assays need to be performed in a short amount of time. With respect to using a centrifuge as the separator, Butz teaches that it common to either magnetic separation (as in Ammann et al) or centrifugation to separate target analytes from unwanted substances (col. 6, lines 51-65). It would have been obvious to one of ordinary skill in the art to

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incorporate a centrifuge in the system of Ammann et al to provide a means for separating the target material from the fluid suspensions.

6. Claims 13-16 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amman et al in view of US Patent 5,047,210 to Melet.

With respect to claims 13-16 and 30, Ammann et al teach that the pipette assembly comprises a liquid drawing section and nozzles (pipette), as well as a vertical movement mechanism (robot). The reference fails to teach an incline mechanism.

Melet teaches a device for presenting receptacles in an automatic analyzer. The device includes a means for inclining the receptacles so that they are better suited for presentation in an analyzer, in particular so the receptacles allow better sample removal. See col. 2, lines 21-34; col. 4, lines 62-68.

It would have been obvious to one of ordinary skill in the art to incorporate an inclining means in the system of Ammann et al to allow the receptacles to tip in a manner that will allow better sample removal with the pipette assembly.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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